

**Ethylene Oxide (EtO) Commercial Sterilization  
Section 114 Survey**

**Instructions Document**

**(For Companies/Facilities that Responded to the December 2019 Questionnaire)**

**Note: This special version of Instructions Document should be used only if your company responded to the December 2019 section 114 questionnaire issued by the U.S. Environmental Protection Agency (EPA). If you did not respond to the December 2019 questionnaire, please do not use this version of the Instructions Document. Instead, please use the general version of Instructions Document available on the EPA's website.**

**I. Introduction**

Under the authority of section 114 of the Clean Air Act, this questionnaire is to be completed for operations at all facilities wholly owned by your company that are part of the ethylene oxide commercial sterilization source category, including those that may be subject to the requirements of 40 CFR part 63, subpart O. The operations for EtO commercial sterilization may include sterilizer chambers, chamber exhaust vents, aeration rooms, and associated fugitive emissions.

Similar to the December 2019 questionnaire, this current questionnaire consists of a main file and three (3) supplements, in the form of Microsoft Excel workbooks, to allow for submission of information requested for operations in the EtO commercial sterilization source category. The supplements only need to be used if additional space is needed. This specific Instructions Document includes instructions on responding to the new questions in this current questionnaire. Since you have responded to the December 2019 questionnaire, you are required to respond to only the new questions in this current questionnaire, which are clearly marked in the Excel workbooks.

All recipients must complete the new questions and return all the Excel workbooks by the date specified in the section 114 transmittal letter. Please see the contact information in **Section VI** below if you have questions regarding this request.

**II. About the Pre-filled Questionnaire and Supplements**

As you responded to the December 2019 questionnaire previously, you will receive a new main questionnaire and applicable supplements for each facility, which are pre-filled with the data you submitted last time. The additional documents you provided either as standalone files or as attachments to the "Documents" worksheet of the main questionnaire are not included. The pre-filled Excel workbooks shared with you are named to reflect the company, city, and state

for each facility. Please make sure to use the facility-specific workbooks for each EtO commercial sterilization facility in your current response.

The pre-filled Excel workbooks are loaded on the thumb drive that is mailed to you in this package. The thumb drive is encrypted with a password (case-sensitive): **EtO114ICR**.

The pre-filled workbooks do not contain any confidential business information (CBI). The data fields that you claimed to be CBI previously are marked with a “CBI” designation in red shading (see Picture 1 below). You are required to respond to only the new questions at this time. The pre-filled data fields are locked and protected from further edits.

The data fields (questions) are marked in 2 different colors:

- The same questions you responded to in the December 2019 ICR are marked in gray shading (see Field A-36 in Picture 1, and Field E-1 in Picture 2 for example). The data you provided previously are pre-filled under the questions in the gray data fields. These data fields are locked and protected, as mentioned above.
- The new questions in this ICR are marked in green shading (see Field B-1 in Picture 2 for example). Please respond to the new questions in these green data fields.

Field #	A-36	
Data	EtO usage at your facility for the last 5 calendar years	
Instruction	Specify the calendar year. Select from the dropdown menu in this column	Enter the corresponding EtO usage in this column (pounds)
Response	2018	CBI

Picture 1. Pre-filled cells in which CBI was claimed previously, in the non-CBI workbooks

Field #	E-1	B-1
Data	Sterilizer unit ID	Room area in which sterilizer unit is located
Instruction	Enter from permit description, if available.	Select from the dropdown menu. Scroll up to see
Response		

Picture 2. Old questions/data fields in gray shading vs. new questions/data fields in green shading

Please scroll down and across each worksheet and respond to the new questions that are in green shading in all sections, except Section M (which may be used should you need space to provide any additional information). You may use the checklist at the end of this Instructions Document to confirm that you have completed all the new questions in this questionnaire.

You may also receive facility-specific plain text documents that complement the pre-filled Excel workbooks. The plain text documents contain explanations on the key issues discovered and any accommodations made when data provided in your original response were pre-filled into the new Excel workbooks.

Please note, in the main questionnaire and supplements, that data fields for “annual” costs do not mean “annualized” cost. Annual costs represent expenses incurred annually to perform

routine activities. You must specify the dollar year for each cost-related data field in the designated column. Please use a consistent dollar year throughout the survey, if possible.

### III. Naming Conventions for Your Questionnaire, Supplements and Documents

Before submitting your questionnaire, supplements (if used) and documents to the EPA, please ensure that you adhere to the following naming conventions:

- CBI version of Excel workbooks with responses

[Company]\_[CityState]\_EtO\_114ICR\_Main\_CBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup1\_CBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup2\_CBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup3\_CBI

*Example filename: Acme\_JonestownMN\_EtO\_114ICR\_Main\_CBI.xlsx*

- Non-CBI version of Excel workbooks with responses

[Company]\_[CityState]\_EtO\_114ICR\_Main\_NonCBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup1\_NonCBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup2\_NonCBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup3\_NonCBI

*Example filename: Acme\_JonestownMN\_EtO\_114ICR\_Main\_NonCBI.xlsx*

- Documents (For Data Field L-7)

[Company]\_[CityState]\_[L-7-numbering, if multiple documents are provided]\_[CBI/NonCBI]

*Example filename: Acme\_JonestownMN\_L-7-1\_NonCBI.pdf*

*Acme\_JonestownMN\_L-7-3\_CBI.pdf*

### IV. Procedure for Creating the non-CBI and CBI Versions of Your Response

To ensure safe and appropriate handling of any CBI data that you may provide, each “green” worksheet (where facility information is to be entered) in the main questionnaire and supplements contains a question in Cell N2 asking whether any CBI is entered in this specific worksheet. This question must always be completed by selecting from the dropdown menu in Cell N2. After you respond to the new questions on each worksheet, please confirm that Cell N2 is up to date before moving to the next worksheet (e.g., if there is no CBI in the pre-filled data, but your response to the new questions contains CBI, Cell N2 should then be updated to “Yes”).

As mentioned above, the new workbooks that are shared with you are pre-filled with non-CBI data only. Please follow the procedures below to create the CBI and non-CBI versions of your response, respectively.

- (1) For each facility, save the workbooks (main questionnaire and any supplements) that are shared with you. These workbooks are named "...\_Template".
- (2) If there is no CBI in the new data you are going to submit this time, change the file name to "...\_NonCBI" according to **Section III**, then skip to step (7). If there is CBI in the new data, change the file name to "...\_CBI" according to **Section III**, then continue to step (3). This workbook will be the CBI version of your response.
- (3) Review each worksheet and respond to the new questions with full, real data including CBI.
  - Leave the data field blank if you do not have any data to provide to the EPA. Please do not enter "0", "N/A", "Not Applicable", or any other text. If any data requested does not apply to your facility, please enter "N/A" or "Not Applicable" as appropriate.
  - Enter your actual CBI data into the appropriate cells, then manually shade each cell containing CBI in red. These cells should look like the example shown in Picture 3 below. Do not shade the entire table if CBI is only entered in certain cells.

A-39.1	
Packaging material used for products sterilized with EtO	
Specify the packaging material used for products sterilized with EtO at your facility	Enter the percent by volume of product sterilized with EtO that uses this packaging material (%)
Cardboard	60.00%

Picture 3. Sample CBI data field in the CBI version of response, with real CBI data

- Remember to select "Yes" from the dropdown menu in Cell N2 if CBI is entered in this worksheet, as shown in Picture 4 below.

Does any information entered on this worksheet contain confidential business information (CBI)? Specify in <b>Cell N2</b> on the right → <b>Be sure to shade in red all cells with real CBI data in the CBI version</b> After creating the <b>non-CBI version</b> , select and copy the Sample CBI Cell (Cell O2) and paste directly into each cell with real CBI data. <b>Make sure all cells that contained CBI look the same as the sample CBI cell (Cell O2)</b> before saving the non-CBI version of your response.	
Yes	CBI Sample CBI Cell (above)

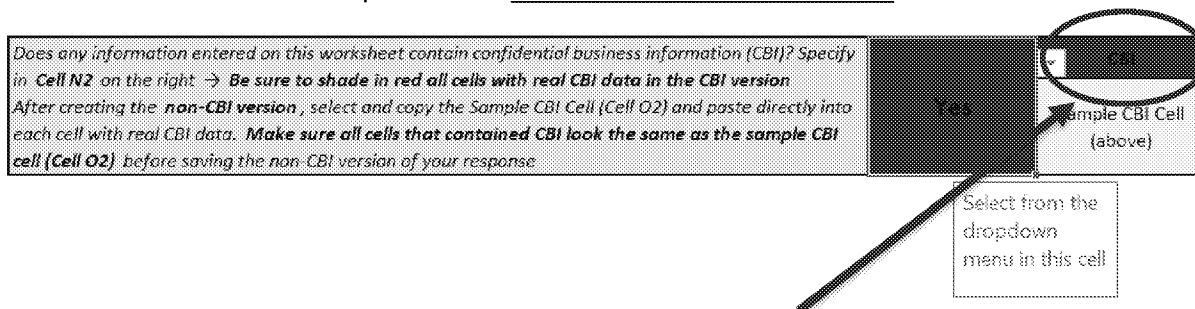
Select from the dropdown menu in this cell

Picture 4. Select "Yes" in Cell N2 if CBI is entered in this worksheet

- To submit documents requested in the new data field L-7, please go to "Documents" worksheet and specify in the designated columns the total number of CBI vs. non-CBI documents you intend to submit to the EPA either as (1) attachments to this

worksheet or (2) individual files via a media. The quantities of documents are non-CBI by default. If you choose to provide the documents as attachments, include all the CBI and non-CBI documents you would like to submit. Please attach only 1 document to each cell, and shade in red all cells containing CBI documents. There is no sample CBI cell in this worksheet.

- (4) In the "Certification" worksheet, check the applicable boxes to acknowledge appropriate handling of CBI in this workbook.
- (5) When you are finished, make sure every data field that contains CBI looks the same as the example in Picture 3, and Cell N2 on each "green" worksheet is up to date. Then save and close this workbook.
- (6) Create a copy of the workbook, and change its file name to "...\_NonCBI" according to **Section III**. This workbook will be the non-CBI version of your response upon completion.
- (7) Review each worksheet and make sure that only non-CBI data are entered to respond to the new questions in the green data fields.
  - Again, please leave the data field blank if you do not have any data to provide to the EPA. Do not enter "0", "N/A", "Not Applicable", or any other text. If any data requested does not apply to your facility, please enter "N/A" or "Not Applicable" as appropriate.
  - To hide and protect your CBI data, copy the sample CBI cell (as shown in Picture 5 below) and paste into the cell(s) containing CBI. Do not change your answer in Cell N2. When you are finished, every data field that contained CBI before should look the same as the sample CBI cell (see the example in Picture 6 below).
    - If a data field contains merged cells across multiple rows or columns, copying and pasting the sample CBI cell may result in duplicate sample CBI cells or missing formatting. In this case, please (1) use the "merge across" feature of Excel to combine those duplicate cells, and/or (2) manually shade the cells back in red. In the end, there should be only 1 cell with the same formatting of the sample CBI cell in each row of each data field.



Picture 5. Sample CBI cell (Cell O2)

- If you have attached documents for data field L-7 in the CBI version of your response, please remove all the CBI documents and preserve only the non-CBI

documents in the “Documents” worksheet. Do not change the total number of CBI vs. non-CBI documents entered in the designated columns. This worksheet should then contain only the non-CBI documents you would like to submit.

A-39.1	
Packaging material used for products sterilized with EtO	
Specify the packaging material used for products sterilized with EtO at your facility	Enter the percent by volume of product sterilized with EtO that uses this packaging material (%)
Cardboard	CBI

Picture 6. Sample CBI data field in the non-CBI version of response, without actual CBI data entry

- (8) Check and update your entries in the “Certification” worksheet.
- (9) When you are finished, make sure there are no CBI data or documents in this non-CBI version of your response, and every data field that contained CBI before looks the same as the sample CBI cell. Then save and close this workbook.

Once completed, the CBI version of your response (main questionnaire and any supplement) must contain the full data and documents that you wish to submit to the EPA, while the non-CBI version must only contain the non-CBI portion of the data and documents. Please submit both the CBI and non-CBI versions of your response to the EPA following the submittal procedures specified in **Section V** below.

## V. Instructions for Submitting Your Responses

For the non-CBI version of your completed Excel workbooks (main questionnaire and supplements), you may submit using one of the following methods.

- Email

For files that are less than 10 MB, email your non-CBI response to Ms. Charlene Spells at [Spells.Charlene@epa.gov](mailto:Spells.Charlene@epa.gov) with a subject line of “EtO Section 114 Survey Response to New Questions for [Company] [CityState]”

- Mail

You may save your files on a media such as thumb drive, CD or DVD, and mail to:

*Ethylene Oxide Commercial Sterilization Section 114 Survey Response  
U.S. EPA Office of Air Quality Planning and Standards  
Sector Policies and Programs Division, Fuels and Incineration Group  
Mail Code E143-05  
109 T.W. Alexander Drive  
Research Triangle Park, NC 27711*

For the CBI version (full version) of your completed Excel workbooks (main questionnaire and supplements), you must save your files on a separate media such as thumb drive, CD, or DVD. Please clearly mark the media with "Confidential Business Information," and mail to:

*U.S. EPA Office of Air Quality Planning and Standards  
U.S. EPA Mailroom (C404-02)  
Attn: Ms. Tiffany Purifoy, Document Control Officer (ESD #322)  
109 T.W. Alexander Drive  
Research Triangle Park, NC 27711*

If you choose to submit your documents as standalone PDF files, all the documents must be saved on the same media with your Excel workbooks (main questionnaire and supplements). The CBI version of your Excel workbooks should be complemented by all the CBI and non-CBI documents, while the non-CBI version of your Excel workbooks should be complemented by only the non-CBI documents.

**DO NOT ELECTRONICALLY TRANSMIT CBI (e.g., via email, fax or ftp) TO THE EPA.**

## **VI. Contact Information**

For general questions regarding this request, please contact Ms. Charlene Spells, Office of Air and Radiation, U.S. EPA, at (919) 541-5255 or [Spells.Charlene@epa.gov](mailto:Spells.Charlene@epa.gov).

For questions on the pre-filled Excel workbooks (main questionnaire and supplements) and this Instructions Document, please contact Mr. Jeremy Guo, Air Quality Engineering, RTI International, at [jjg@rti.org](mailto:jjg@rti.org).

### Checklist of New Data Fields in the August 2021 Questionnaire

Worksheet	Table	New Field Numbers
Facility Details	Table 5. Facility-level Data	A-45, A-46, A-47
	Table 6. Materials Sterilized with EtO	A-39.1, A-39.2
	Table 7. Materials Sterilized with Non-EtO Techniques and Approaches	A-48, A-49, A-50, A-51
Room Area	Table 4. Room Area Controls	B-60.1 and B-62
EtO & EG Storage	Section C. EtO Drum and Container Storage	C-0
	Section D. Ethylene Glycol (EG) Tanks	D-31
Sterilizer Chambers	Table 2. Sterilizer Chamber Operation and Monitoring Characteristics	B-1
	Table 3. Control Characteristics for Sterilizer Chambers	E-72.1, E-74.1, E-74.2, E-110.1
	Table 4. Control Characteristics for Sterilizer Chambers (continued)	E-132.1
Aeration	Table 1. Aeration that Occurs in Separate Unit (Aeration Room & Aeration Cell/Chamber)	B-1, F-8.1, F-42.1
APCD Details	Table 2. Dry-bed Scrubber	H-14.1, H-16.1, H-16.2
	Table 3. Catalytic Oxidizer & Combination Water Balancer/Catalytic Oxidizer	H-32.1, H-34.1, H-34.2, H-35.1, H-35.2, H-35.3
EtO Monitoring	Table 1. Personal Monitoring (Badges) for EtO	I-2.1, I-3.1, I-3.2
	Table 2. Room Area Monitoring for EtO	I-9.1, I-9.2
Miscellaneous	Table 1. EtO and Facility Operation	L-7
	Table 2. Standalone Non-Colocated Warehouse, Distribution Center, or Enclosed Building for Sterilized Products	L-8, L-9, L-10, L-11
	Table 3. Alternative Sterilization	L-12, L-13